New Protocol Submission Procedures

This is a short overview of requirements for conducting research at Lexington VAMC. The purpose is to provide instructions concerning the process of obtaining research approval at this facility.

A. Professional Qualifications to perform Research

All key research study personnel must have an annual Scope of Practice. Investigators need to be credentialed to conduct research involving human subjects.

Training of investigators (and all key research study personnel) is an integral part of maintaining high standards in the research program at Lexington VAMC. Training required will depend on the type of research conducted. Training may consist of online courses and/or review of existing presentations.

In order to determine the training required for a particular protocol, please determine the type of research that will be conducted (Part B) and contact the individuals associated with the particular committee/subcommittee listed in Part C.

B. Proposal Submission – Forms required

1) Forms required from ALL research proposals (R&D Committee):

a) Project data sheet (10-1436)
b) Investigator data (page 18)
c) Investigator CV
d) Protocol
e) Attachment A
f) Attachment B
g) Scope of Practice
h) Conflict of Interest
i) Safety Subcommittee Forms (Consultation form; Training form; SRS 10-0398)

2) Forms required to conduct Human Subjects Research (IRB Subcommittee):

a) IRB Application
b) Privacy/ISO Review Checklist
c) Form 31a
d) Expedited Form (if applicable)

<u>If exempt from IRB review, please include:</u>

e) Exempt Form
f) Data Collection Forms/Tools/Case Report Forms
g) Request for Waiver or Alteration of Informed Consent
h) Request for HIPAA Waiver

<u>For full IRB review, please include:</u>

i) VA Research Informed Consent Form
j) Participant Instructions
k) Recruitment Materials
l) Vulnerable Population Supplement
m) VA Investigational Drug Information (VA Form 10-9012)
n) Questionnaires or Surveys with OMB Approval
o) Data Collection Forms/Tools/Case Report Forms

p) Consent for Use of Picture and/or Voice (VA Form 12-3202)
q) Request for an Authorization to Release Medical Records or Health Information (VA Form 10-5345)
r) HIPAA Authorization

3) Forms required to conduct Animal Research (IACUC Subcommittee):

a) Animal Component of Research Protocol (ACORP)
b) ACORP Consultation Form
c) Animal Component of Research Protocol Signoff Appendix 1: Use of a Non-VA Facility to House Animals Purchased with VA or VA Research and Education Corporation Funds
d) Appendix 2: Antibody Production
e) Appendix 3: Test Substances
f) Appendix 4: Antemortem Specimen Collection
g) Appendix 5: Surgery
h) Appendix 6: Special Husbandry and Procedures
i) Appendix 7: Request to Use Patient Care Procedural Areas for Animal Studies
j) Appendix 8: Request to Use Explosive Agent in the Animal Facility or in Animals
k) Appendix 9: Additional Local Information

C. Contact Information

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